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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/552,272	04/19/2000	Li Fang	913.6600CIP	3198

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EXAMINER

EPPS, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 11/19/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/552,272

Applicant(s)

FANG ET AL.

Examiner

Janet L Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicants have amended the first paragraph of page 1 of the specification as filed to recite wherein application 09/293,427 is a CIP of 09/796,945, and wherein 09/796,945 is a CIP of 09/203,806. Applicant's continuity data is incorrect since 09/293,427 is a CIP of 08/796,945 not 09/796,945, and 08/796,945 claims priority to the provisional application 60/013,922. Application 08/796,945 is not a CIP of 09/203,806. Additionally, the US Patent 5,714,575 was not issued from application 09/203,806, the correct application is 08/203,806.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-4, 6-9, 11-13, 16-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims read on isolated ribonucleic acid molecules that prolong the expression of a cold shock inducible gene under conditions that elicit the cold shock response in a bacterium, non-coding ribonucleic acid molecules that enhance the translation of a cold shock inducible gene under conditions that elicit the cold shock response of a bacterium, nucleic acid vectors that enhance translation of a gene under conditions that elicit a cold-shock response in a bacterium, a nucleic acid vector that directs the prolonged expression and enhances the

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translation of a gene under conditions of physiological stress that elicit a cold shock response of a bacterium, and methods of using said vector that enhances translation of a gene under conditions that elicit a cold shock response in a bacterium.

The instant claims read on a broad genus of nucleic acid molecules that function to prolong the expression of a cold shock inducible gene, wherein said nucleic acid comprises a 5'-UTR of a cold shock inducible gene, sequences that are substantially homologous to said cold shock inducible genes (see claim 2), including all polymorphic and allelic variants of said cold shock inducible genes, and sequences isolated from any organism. However, Applicant's describes only the 5'-UTR of the cold shock inducible genes according to the *cspA*, *cspB*, and *csdA* genes. Applicant's description of the nucleic acid molecules according to the *cspA*, *cspB*, and *csdA* genes, is not commensurate in scope with the broad genus of nucleic acid molecules encompassed by the instant claims, such that the ordinary skilled artisan can use the description set forth in the specification as filed to predict the structures of all members of the broad genus of molecules encompassed by the instant claims. It is evident that further experimentation would be required in order to identify those sequences that are substantially homologous to the sequences of (for example) the *cspA*, *cspB*, and *csdA* genes, and furthermore to identify those substantially homologous sequences that function to prolong the expression of a cold shock inducible gene, or wherein said sequence functions to enhance translation of a gene under conditions that elicit a cold shock response in a bacterium.

See the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, "Written Description" Requirement. These guidelines state: "[T]o satisfy the written description

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requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention."

Moreover, since it appears that further experimentation is required to identity the full scope of the claimed genus of nucleic acid molecules encompassed by the instant claims, it is concluded that other than the nucleic acid molecules encompassing the 5' UTR of the *cspA*, *cspB*, and *csdA* genes, the full scope of the claimed invention was not "ready for patenting" at the time the invention was filed. Therefore, applicant was not in possession of the full scope of the claimed invention at the time of filing of the instant application.

Response to Arguments

4. Claims 1-15 remain rejected under 35 U.S.C. 102(b) as being anticipated by Goldstein et al. for the reasons of record set forth in the Official Action mailed 9-13-01.

Applicant's arguments filed 2-22-02 have been fully considered but they are not persuasive. Applicants traverse the instant claims on the grounds that in regards to claims 1-15, Goldstein makes no mention of even a single RNA molecule. However, contrary to Applicant's assertions, although an RNA molecule is not mentioned in the reference, an RNA molecule

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produced from the nucleic acid sequence encoding the entire *cspA* gene cloned into the pJJG01 vector is inherently present in the instant reference since the reference discloses *E. coli* bacteria comprises the pJJG01 vector, and the sequence *cspA* gene sequence comprises promoter elements that are recognized by RNA polymerase present in *E. coli* bacteria (see page 286, col. 2, paragraph 2, lines 7-8 and Figure 5B).

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

6. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Oppenheim et al. (US Patent No. 5,726,039) or Oppenheim et al. (US Patent No. 5,654,169).

The instant claims read on isolated ribonucleic acid molecules that prolong the expression of a cold shock inducible gene under conditions that elicit the cold shock response in a bacterium, wherein said molecules comprise a 5'-UTR of a cold shock inducible gene or a substantially homologous sequence thereof. Furthermore, wherein said 5'-UTR is a 5'-UTR of a cold-shock inducible gene selected from the group consisting of *cspA*, *cspB*, and *csdA*, wherein the 5'-UTR comprises a cold box or a substantially homologous sequence thereof.

Applicants argue (see page 12 of the response filed 2-22-02) that the inventions of both Oppenheim et al. patents are drawn to DNA molecules and not ribonucleic acid molecules. However, contrary to Applicant's assertions, it is noted that, for example, endogenous *cspA* mRNA, and mRNA comprising the *cspA* 5'-UTR and a *lacZ* fusion are also disclosed (see col. 13, lines 5-20; US Patent 5,654,169; col. 14, lines 40-63, US Patent 5,726,039).

Oppenheim et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

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7. The allowability of claims 28, 38-50 and 53, set forth in the prior Office Action is withdrawn in view of the new grounds of rejection set forth above.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 9:00AM to 7:00 PM.

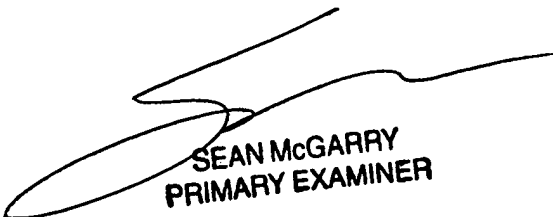
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE

November 15, 2002


SEAN MCGARRY
PRIMARY EXAMINER